IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSSISSIPI
NORTHERN DIVISION

CHESTER RANDOLPH PIPPIN
AND GWEN PIPPIN **PLAINTIFF**

V. **CIVIL ACTION NO. 3:22-CV-431-HTW-LGI**

ENDOLOGIX, INC., **DEFENDANT**

ORDER

Before this Court is Defendant Endologix, Inc.'s ("Defendant" or "Endologix") **Motion to Dismiss [Dkt. No. 5]**, wherein Defendant seeks dismissal of all claims brought by Plaintiffs Chester Randolph Pippin and Gwen Pippin ("Plaintiffs") under Rule 12(b)(6)[1] of the Federal Rules of Civil Procedure. This Court, having examined the pleadings, considered the parties' briefs, and being otherwise fully advised in the premises, now rules as follows: Defendant's Motion to Dismiss is GRANTED IN PART and DENIED IN PART, for the reasons more fully explained below.

I. JURISDICTION AND VENUE

This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a)[2], as complete diversity of citizenship exists and the amount in controversy exceeds $75,000, exclusive of interest and costs. Plaintiffs are citizens of Mississippi, while Endologix is incorporated in Delaware and

[1] b) How to Present Defenses. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion: … 6) failure to state a claim upon which relief can be granted;
Fed. R. Civ. P. 12

[2] Title 28 U.S.C. § 1332:
(a) The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between—
(1) Citizens of different States…

maintains its principal place of business in California. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)[3], as the underlying events—including the medical implantation and related treatment—occurred in this district.

II. BACKGROUND

This case centers on allegations arising from the failure of a medical device, the AFX Endovascular AAA System, used to treat a dangerous and potentially fatal medical condition known as an abdominal aortic aneurysm (AAA). AAAs occur when the wall of the aorta, the body's main artery, weakens and bulges outward, creating a risk of rupture and internal hemorrhage. Endovascular aneurysm repair (EVAR) is a common alternative to open heart surgery, and involves the implantation of a stent graft device, like the AFX, that provides a new path for blood flow and shields the weakened vessel wall from further pressure.

In 2012, Plaintiff Chester Pippin ("Mr. Pippin") underwent EVAR surgery, during which physicians implanted an AFX Endovascular AAA System manufactured by Defendant Endologix, Inc. Class III medical devices are those deemed by the U.S. Food and Drug Administration (FDA) to pose the greatest potential risk to patient health. These devices are typically used to sustain or support life, are implanted for extended periods, or present a potential for serious injury or death if they fail. As a result, Class III devices are subject to the most rigorous regulatory controls under

[3] **(b) Venue in general.**--A civil action may be brought in--
(1) a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located;
(2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated; or
(3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court's personal jurisdiction with respect to such action

28 U.S.C.A. § 1391 (West).

the Food, Drug, and Cosmetic Act[4]. Manufacturers must obtain FDA approval through the Premarket Approval (PMA) process, which requires scientific evidence demonstrating the device's safety and effectiveness, as well as providing detailed information regarding the device's design, manufacturing, and labeling[5]. The version used in Mr. Pippin's surgery contained a proprietary material known as Strata™, which Plaintiffs allege was later shown to be susceptible to fabric failures resulting in Type III endoleaks. A Type III endoleak occurs when blood reenters the aneurysm sac through separations in the graft's structure, potentially leading to continued aneurysm expansion or rupture.

Mr. Pippin was asymptomatic for several years, until August 2019, when he experienced severe abdominal and back pain. Diagnostic evaluations revealed a ruptured aneurysm and evidence of a Type III endoleak. He required emergency surgical intervention, followed by several additional operations, including an open heart repair. Plaintiffs allege that these procedures caused Mr. Pippin to suffer long-term complications, including renal failure and diminished quality of life. Plaintiff Gwenn Pippin ("Mrs. Pippin") claims derivative damages, including loss of consortium and income, resulting from her need to care for her husband.

According to Plaintiffs, Endologix knew of the risks associated with the Strata-based AFX device well before issuing a formal recall in December 2016. The recall, according to the U.S. Food and Drug Administration, was initiated due to concerns about the structural integrity of the AFX device and its tendency to develop Type III endoleaks.

[4] See 21 U.S.C. § 360c(a)(1)(C); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–78 (1996).

[5] See 21 C.F.R. § 814.1 et seq.; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–20 (2008).

The FDA classified the recall as a Class II recall, which signifies a situation in which use of the product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote. Plaintiffs allege that by the time of the recall, Endologix had received multiple reports indicating elevated rates of endoleaks, but delayed both the recall and public disclosure. Plaintiffs further assert that Endologix continued distributing modified versions of the AFX device using the same Strata material after the company was aware of its shortcomings.

In 2020, Endologix filed for Chapter 11 bankruptcy, a legal process under the United States Bankruptcy Code designed primarily for the reorganization of financially distressed companies. Chapter 11 allows a debtor to propose a plan of reorganization to keep its business alive and pay creditors over time.

The process typically involves several key steps: filing a voluntary petition, submitting schedules of assets and liabilities, formulating a reorganization plan, soliciting creditor votes, and obtaining court confirmation of the plan. Once the plan is confirmed by the court, it binds the debtor and all creditors, and the debtor is discharged from liabilities that arose before the plan's confirmation date, subject to certain exceptions. See 11 U.S.C. §§ 1101–1174 (governing Chapter 11 cases); 11 U.S.C. § 1141(d)(1)(A) (effect of confirmation); *United States v. Whiting Pools, Inc.*, 462 U.S. 198, 203–04 (1983) (explaining that Chapter 11 is designed to allow a financially distressed business to reorganize and continue operations); *In re MCorp Fin., Inc.*, 137 B.R. 219, 225 (Bankr. S.D. Tex. 1992) (summarizing the procedural steps in a Chapter 11 case).

The legal and factual implications of this bankruptcy—including whether Plaintiffs received adequate notice and whether their claims were known or reasonably ascertainable—form a central component of the dispute and are addressed in greater detail in the analysis that follows.

III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) provides for dismissal when a complaint fails to state a claim upon which relief can be granted. The purpose of Rule 12(b)(6) is to test the legal sufficiency of the complaint, not to resolve contested facts or determine the merits of the case. In evaluating such a motion, the Court accepts as true all well-pleaded factual allegations and draws all reasonable inferences in the plaintiff's favor. See *Erickson v. Pardus*, 551 U.S. 89, 94 (2007).

To withstand dismissal, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible when the factual content allows the court to draw a reasonable inference that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While the plausibility standard is not a "probability requirement," it does require more than a mere possibility that a defendant acted unlawfully. Id. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, are insufficient. Id.

In the context of product liability, especially where federal preemption is at issue, courts must scrutinize whether the complaint alleges violations of specific federal requirements and whether such allegations track duties imposed under state law. See *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012). Additionally, courts may consider documents that are referenced in the complaint and central to the claims, as well as matters of public record. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498–99 (5th Cir. 2000).

This standard ensures that only complaints which allege concrete, plausible, and legally cognizable claims proceed beyond the pleading stage and into discovery.

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal of complaints that fail to state a claim upon which relief can be granted. To survive dismissal, a complaint must contain enough factual content to allow a court to draw a reasonable inference that the defendant is liable. See *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court must accept well-pleaded facts as true and view them in the light most favorable to the non-moving party. Conclusory allegations or legal conclusions unsupported by factual assertions do not meet this standard.

IV. DISCUSSION

The parties present this Court with complex legal and factual questions arising from the implantation of a Class III medical device, subsequent adverse events, and the legal effect of the manufacturer's bankruptcy. Each issue involves overlapping areas of federal and state law, as well as the interplay between regulatory compliance and tort liability. The Court evaluates each argument below with attention to established Fifth Circuit precedent and relevant statutory authority.

A. Preemption

The doctrine of federal preemption stems from the Supremacy Clause of the United States Constitution[6], and in the context of medical devices, is governed by the Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act (FDCA). Under 21 U.S.C. § 360k(a), states may not impose requirements "different from, or in addition to" those established by the FDA. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court

[6] This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, cl. 2

affirmed that state tort claims challenging the safety or effectiveness of a Class III device approved through the FDA's PMA process are expressly preempted.

The United States Supreme Court also recognized in *Riegel*, and another case *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state claims based on duties "parallel" to federal requirements may proceed. The Fifth Circuit has applied this principle to allow claims alleging violations of federal regulations that are also actionable under state law. See *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011).

In the instant case, Plaintiffs allege the following causes of action under state law: (1) Manufacturing Defect; (2) Design Defect; (3) Failure to warn; (4) Negligence; (5) Loss of Consortium. This Court now analyzes each of these in turn.

1. Manufacturing Defect

Plaintiffs allege that the AFX device implanted in Mr. Pippin deviated from FDA-approved specifications and federal regulatory requirements under the Current Good Manufacturing Practices (CGMPs)[7]. Under Mississippi law, a plaintiff must show that the product deviated in a material way from its intended design and that the deviation caused the plaintiff's injuries. See Miss. Code Ann. § 11-1-63(a)(1)[8]. The Complaint includes allegations that Endologix improperly

[7] Current Good Manufacturing Practices (CGMPs or cGMPs) are a set of regulations enforced by the U.S. Food and Drug Administration (FDA) to ensure that products—especially pharmaceuticals, biologics, medical devices, and food—are produced consistently and meet quality standards.U.S. Food and Drug Administration (FDA). (2023). *Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR Part 211.* Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211.

[8] Subject to the provisions of Section 11-1-64, in any action for damages caused by a product, including, but not limited to, any action based on a theory of strict liability in tort, negligence or breach of implied warranty, except for commercial damage to the product itself:

- (a) The manufacturer, designer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller:
  - (i)
    - 1. The product was defective because it deviated in a material way from the manufacturer's or designer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or

tested and validated the AFX device, failed to detect known risks, and utilized methods for evaluating device failure that did not comply with federal standards. At this stage, those allegations plausibly state a manufacturing defect claim under Mississippi law and, because they are premised on violations of FDA requirements, they also avoid federal preemption. See *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012).

2. Design Defect

Design defect claims under Mississippi law require Plaintiffs to prove that a feasible alternative design existed that would have prevented the harm. See *Elliott v. El Paso Corp.*, 181 So. 3d 263, 270 (Miss. 2015). Plaintiffs allege that the Strata™ material was unreasonably dangerous and resulted in a greater incidence of Type III endoleaks compared to other materials available at the time.

AFX system design was approved through the FDA's PMA process. As explained above, a state-law claim challenging that design is generally preempted unless it parallels federal requirements. Plaintiffs do not allege that the design itself violated FDA regulations. Accordingly, to the extent Plaintiffs challenge the AFX's design independent of FDA standards, the claim is preempted. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

- 2. The product was defective because it failed to contain adequate warnings or instructions, or
- 3. The product was designed in a defective manner, or
- 4. The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product; and

- (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
- (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

3. Failure to Warn

Mississippi applies the learned intermediary doctrine, under which a manufacturer discharges its duty to warn by informing the prescribing physician of risks associated with a medical device. See *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988). Plaintiffs allege that Endologix failed to update warnings to reflect post-market data, misrepresented the true rate of Type III endoleaks, and delayed notifying physicians of the Strata recall. Plaintiffs further claim that this failure was a violation of federal post-market surveillance regulations. If proven, these allegations may constitute both a violation of state law and a parallel violation of federal law, and thus the failure-to-warn claim survives dismissal.

4. Negligence

Plaintiffs assert that Endologix negligently designed, tested, manufactured, marketed, and monitored the AFX device. Under Mississippi law, negligence requires proof of a duty, breach, causation, and damages. See *Donald v. AMOCO Prod. Co.*, 735 So. 2d 161, 174 (Miss. 1999). The factual allegations concerning post-market conduct, testing failures, and mishandled recalls are sufficient to state a plausible negligence claim. To the extent the negligence allegations rest on violations of FDA requirements, they are not preempted. See *Bausch v. Stryker Corp.*, 630 F.3d 546, 554 (7th Cir. 2010).

5. Loss of Consortium

Loss of consortium is a derivative claim that rises and falls with the viability of the injured spouse's underlying tort claims. See *Flight Line, Inc. v. Tanksley*, 608 So. 2d 1149, 1163 (Miss. 1992). Because Mr. Pippin's manufacturing, negligence, and failure-to-warn claims survive dismissal, Mrs. Pippin's claim for loss of consortium likewise survives at this stage of the litigation. – Mrs. Pippin brings a derivative claim based on Mr. Pippin's injuries, seeking

compensation for loss of companionship, support, and income resulting from her husband's condition.

Having resolved the question of federal preemption, the Court next turns to the issue of whether Plaintiffs' claims are independently barred by Endologix's 2020 Chapter 11 bankruptcy discharge. This transition shifts the Court's analysis from regulatory compliance and tort liability to matters of bankruptcy law and constitutional due process.

B. Bankruptcy Discharge

Bankruptcy discharge under Chapter 11 generally releases a debtor from all claims that arose before confirmation of the bankruptcy plan. See 11 U.S.C. § 1141(d)(1)(A). This discharge is intended to give the debtor a fresh start by extinguishing liabilities, including tort claims that accrued pre-petition. This powerful relief, however, is not absolute. The due process clause of the Fifth Amendment places critical limits on the enforceability of discharge provisions, particularly in relation to notice.

The Fifth Circuit has made clear that a bankruptcy discharge cannot bar the claims of a creditor who was not provided constitutionally adequate notice. In *In re Placid Oil Co.*, 753 F.3d 151 (5th Cir. 2014), the court emphasized that known creditors are entitled to actual, written notice of the bankruptcy proceedings. A known creditor is one whose identity is either known or reasonably ascertainable by the debtor. Similarly, in *In re Eagle Bus Mfg., Inc.*, 62 F.3d 730 (5th Cir. 1995), the court declined to enforce a discharge against tort claimants whose claims arose pre-petition but who were not given meaningful notice or the opportunity to file a proof of claim.

Here, Defendant Endologix asserts that all claims arising from devices implanted before its 2020 Chapter 11 filing are subject to discharge under the confirmed reorganization plan. That argument, while persuasive on its face, is undermined by the Plaintiffs' allegations that they did

not receive any form of actual notice. Plaintiffs allege that Mr. Pippin had multiple revision surgeries and emergency procedures related to a known device defect that was subject to a recall. These medical interventions occurred years before the bankruptcy. Plaintiffs argue that Mr. Pippin's identity and contact information were reasonably ascertainable through medical and sales records, particularly given the 2016 recall of the Strata-based AFX graft.

Courts have distinguished between known and unknown creditors based not only on whether the debtor had actual knowledge of the individual, but also whether the debtor should have known about the creditor through reasonable diligence. See *Tulsa Prof'l Collection Servs., Inc. v. Pope*, 485 U.S. 478, 490–91 (1988). Where a debtor fails to list or notify such a creditor, the discharge does not bind that individual, and his/her claim may proceed notwithstanding the bankruptcy.

Other courts similarly have held that product liability claimants, especially those injured by recalled medical devices, cannot be swept into bankruptcy proceedings without specific notice. In *In re Chemtura Corp.*, 439 B.R. 561 (Bankr. S.D.N.Y. 2010), the court found that a failure to identify claimants who were reasonably discoverable violated due process and nullified the discharge as to those claims. See also *In re Texaco Inc.*, 182 B.R. 937, 955 (Bankr. S.D.N.Y. 1995) (known asbestos claimants with ongoing symptoms required actual notice).

Given these precedents, the Court finds that a dispositive ruling on the discharge issue would be premature. Whether Mr. Pippin was a "known creditor" hinges on questions of fact, including the extent of Endologix's internal records, the nature of its recall-related communications, and its listing of potential claimants during the bankruptcy proceedings. If discovery reveals that Endologix had access to information tying Mr. Pippin to the recalled AFX device and failed to provide notice, the discharge may not apply. If, on the other hand, Endologix

can demonstrate that Mr. Pippin's claim was neither known nor reasonably discoverable, the discharge defense may succeed at summary judgment.

At this stage, taking Plaintiffs' well-pleaded allegations as true, the Court concludes that the defense of bankruptcy discharge is not appropriate for resolution on a Rule 12(b)(6) motion. Plaintiffs have plausibly alleged a lack of notice sufficient to preserve their claims.

V. CONCLUSION

For the foregoing reasons, Defendant's Motion to Dismiss is **GRANTED IN PART and DENIED IN PART**:

- Plaintiffs' claims for **manufacturing defect, failure to warn, negligence, and loss of consortium** are sufficiently pleaded and may proceed.
- To the extent Plaintiffs assert a **design defect** claim that is not tied to violations of FDA requirements, that claim is **DISMISSED WITHOUT PREJUDICE** as preempted.
- The issue of **bankruptcy discharge** remains unresolved pending further development of the record and may be revisited at summary judgment.

SO ORDERED this the 30th day of March, 2025.

/s/HENRY T. WINGATE
UNITED STATES DISTRICT JUDGE